



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

WASHINGTON STATE BOARD OF PHARMACY

September 6, 2007

Mirabeau Park Hotel & Convention Center
North 1100 Sullivan Road (Ponderosa Room)
Spokane WA 99037 Telephone: 509-924-9000
Board Office: (360) 236-4825

CONVENE

Madame Chair Rebecca Hille called the meeting to order at 9:00 a.m. on September 6, 2007.

Board Members present:

Gary Harris, RPh, Vice-Chair
George Roe, RPh
Rosemarie Duffy, RN – Public Member
Susan Teil-Boyer, RPh
Vandana Slatter, PharmD

Board Members absent:

Dan Connolly, RPh

Staff Members Present:

Steven Saxe, Executive Director (Acting)
Lisa Salmi, Executive Manager
Joyce Roper, AAG Advisor
Tim Fuller, Pharmacist Consultant
Cathy Williams, Pharmacist Consultant
Bill Kristin, Pharmacist Investigator
Doreen Beebe, Program Manager

Staff Members absent:

Cheryl Christensen, Support Staff

Mission Statement

The mission of the Board of Pharmacy is to achieve the highest standards in the practice of pharmacy, to promote public health and safety. The Board of Pharmacy will educate and effectively communicate with the profession, the public, the Governor, Legislature, the Department of Health.

Vision Statement

The Washington State Board of Pharmacy leads in creating a climate for the patient-focused practice of pharmacy.

Pharmacists inform, educate, consult, manage drug therapy and provide products as an integral part of an accessible, quality –based health care system.

As an outcome, the citizens of Washington State:

- Are well informed about medications;
- Take responsibility for their health;
- Utilize pharmacists and other health care providers appropriately; and
- Experience the highest level of health and wellness.

Pharmacist Applicant Study Plan

In closed session, Board members Vandana Slatter, Gary Harris and George Roe reviewed and discussed the study plan proposed by pharmacist applicant Priyesh Patel. The Board panel presented its recommendations to the full board. **ACTION:** Susan Teil-Boyer moved that the Board approve the study plan and authorize Mr. Patel to re-take the Multi-State Jurisprudence exam. George Roe second. **MOTION CARRIED 5-0.**

CONSENT AGENDA

- 1.2 Pharmacy & Other Firm Application Approval
 - New & Closed Pharmaceutical 7/1/07 – 8/10/07
- 1.4 Pharmacy Tech Training Program Approval
 - California Paramedical & Tech College, Riverside CA –Kristi Foy
 - San Joaquin Valley College, CA – Obinna Eke
 - United Education Institute, San Diego CA – Nicole Kilday
 - College of Pharmacy University of Baghdad, Iraq – Mofeed Murkus
 - Rite Aid, Oregon – Gregory Olson
 - American College, Los Angeles CA –Jaso Darensbourg
 - Purdue University, Indiana – Timothy Weller
 - Fresno Institute of Technology CA – Julie Brown
 - Walgreens, IL – Andrea Berutti
 - Intellitec Medical Institute -Lorriisa Yancey
 - Gulbarga University, India – Neetu Sharma
 - Seth Govind Raghunath Sable College of Pharmacy, India – Jariti Gupta
 - Landesapoathekerkammer Hessen, Germany – Ellen Hoffmaster
 - St Francis Medical Center, Honolulu HI – Lacey Geise
- 1.5 Collaborative Drug Therapy Agreement Acceptance
 - Peninsula Community Health Services – Various
- 1.6 Automated Drug Dispensing Device Acceptance
 - Propac Pharmacy
 - Hi-School Pharmacy Medicine – On-Time
 - Chesterfield Pharmacy
- 1.7 Sample Distribution Requests
 - Community Health Centers of Snohomish County
- 1.8 Board Minute Approval – July 26, 2007

Items 1.1 – Pharmacist License Application Approval; and 1.3 – Pharmacy Technician Application Approval were deleted from the consent agenda. **ACTION:** George Roe moved that the Board approve 1.2, 1.4, 1.5, 1.6, 1.7 and 1.8 of the consent agenda. Vandana Slatter second. **MOTION CARRIED 6 – 0.**

REPORTS

Acting Executive Director

Steven Saxe *reported:*

- Mr. Saxe provided the Board with an overview of the Health Systems Quality Assurance division restructure and described the interim step of moving the Pharmacy Program under the office of Facilities and Services Licensing. The Executive Director recruitment

for the Board will be revisited once the office Directors are selected and the structure of the Health Professions and Facilities Office is defined.

- Next month, Mr. Saxe will participate on a panel at the Citizens Advocacy Conference addressing “Root Cause Analysis Systems” – promoting patient safety and how to work with the regulatory process.

Executive Manager

Lisa Salmi *reported:*

- New Pharmacist Consultant – Cathy Williams
- Ms. Salmi summarized the Performance Audit Report resulting from an external audit of Health Professions Quality Assurance conducted in 2006 – 2007. The report included thirteen recommendations. Governor Gregorie asked that three of the recommendations be implemented immediately.
 1. Develop specific criteria to address complaints for imminent danger;
 2. Adopt mandatory reporting rules by March 2008; and
 3. Organize credentialing and compliance practices to ensure a timely, consistent and effective process across all professions.
- Ms. Salmi updated the Board on the activities of the Pharmacist Investigators and monthly statistics on investigation and inspections.
 - New Investigator – Dr. Tyler Varnum training update
 - Interview for Chief Investigator scheduled for September 13th.
 - Stan Jeppesen will present information on the PH:ARM Take Back Program to the National Association of State Controlled Substances Authorities annual meeting.
 - Grace Cheung will lead a work group to develop recommendation on appropriate sanctions for medication errors.
 - Jim Doll, Jim Lewis and Stan Jeppesen participate at stakeholder meeting regarding correctional facilities rule development on August 23rd.
 - Quarterly Investigators’ meeting September 12 – 13. George Roe will represent the Board.

Board Member

- Chair Rebecca Hille and Vice-Chair Gary Harris participated in the “Meet Me” calls to discuss the finding of the *Performance Audit*.
- Susan Teil-Boyer requested that Board staff research on the best course of action to address the dangers of Fentanyl patches in treating acute pain. Ms. Boyer suggested that the Board discuss drafting a letter to the DEA to require dispensing by pharmacists.

Assistant Attorney General

Joyce Roper *reported:*

- Briefed the board on the lawsuit challenging the legality of the pharmacies’/pharmacists’ responsibilities rules. A motion to intervene was filed on behalf of several patients who fear discrimination due to HIV and oral contraception. Ms. Roper is working on the case with AAG Pam Anderson and Special AAG Paul Lawrence.

Consultant Pharmacist

Tm Fuller *reported:*

- Strategic National Stockpile activity scheduled for October 31st. Rosemarie Duffy has volunteered to participate. Primary issue concerns medication orders.

- New Naturopathic Physician rules will expand the drug list to include Schedules 3 through 5, requiring registration with the federal Drug Enforcement Administration.

Program Manager

Doreen Beebe *reported:*

- Held Health Professions Section Four new board member orientation – attended by Dan Connolly and Dr. Vandana Slatter, and two members of the Veterinary Board of Governors – Dr Harmon Rogers and public member Holly Bard. The orientation included, in part, an overview of the Department of Health, rule-making, legislative process, administrative procedures act and investigations.
- Citizen Advocacy Center conference October 29 – 31 in Seattle
- Health Professions Quality Assurance Board and Commission Forum – September 27 in Olympia
- The Methamphetamine WorkGroup draft report has been completed and will under go agency review. Ms. Beebe distributed a copy of the draft to members of the Board and provided the timeline for review. The report is due to the Office of Financial Management on October 18th for report to the Legislature by November 1, 2007.
- The survey regarding the proposed rules to require pharmacy technicians to pass a national standardized certification examination is scheduled for distribution next week. Approximately 30 randomly selected board-approved training programs will be asked to respond. The survey will provide information needed to prepare a *Small Business Economic Impact Statement*. Tentative hearing date – January 25, 2008.

PRESENTATIONS

Prevention of Pharmaceutical Diversion. Presentation by Dr. Marc Gonzalez, Director, Law Enforcement Liaison/Education, Purdue Pharma. Dr. Gonzalez presented information on prescription drug abuse and diversion of Controlled Substances. His presentation included information on how to protect your pharmacy and how to recognize fraudulent prescriptions and drug seekers.

- Pharmacy security – physical design
 - Burglaries/Robberies
- Lawful prescribing and prevention of diversion
- Signs of potential abuse problems
- Protecting pharmaceuticals
- Forged/Altered prescriptions
- Fraudulent call in prescriptions
- Tamper-resistant prescriptions
- RxPATROL® - Information Clearinghouse (Patten Analysis Tracking Robberies and Other Losses).

ExcelleRx, Inc. Request to Provide Pharmacy Services to Washington Hospice. Ms. Catherine Woods representing ExcelleRx, Inc. (doing business as Hospice Pharmacia) presented a proposal to provide pharmacy services to hospice inpatients units from its out-of-state pharmacies using automated drug distribution devices (ADDD's).

- Tri-Cities Chaplaincy Hospital In-Patient Unit – 10 beds.

- Hospice nurses must complete board-approved technician training program for authority to stock ADDD's. Rules do not permit nurses to stock.
- ADDD's have finger printing verification
- ExcelleRx (out-of-state) pharmacies
 - Authorizes release of drug from ADDD's
 - Only the drawer containing authorized drug will open.
 - Pharmacy hours – 24 hours service with on-call pharmacist – during after hours.
 - Pharmacist performs remote order entry.
 - Pharmacist reviews prescriptions and patient medical administration records.

ACTION: Rosemarie Duffy moved that the Board approve the proposal by ExcelleRx to provide pharmacy services to Tri-cities Chaplincy's inpatient hospice located in Washington State, with the following stipulations. The hospice must employ a pharmacist consultant (full or part-time). The pharmacist must be licensed and located in Washington and available to provide immediate supervision of a pharmacy technician. All automated drug distribution devices must be stocked by Washington certified pharmacy technician or pharmacist. ExcelleRx is to report back six-months from date of implementation. Gary Harris 2nd. **MOTION CARRIED** George Roe opposed. Vote 4-1

EXECUTIVE SESSION

The Board adjourned at 11:50 a.m. for the Executive Session to discuss personnel issues and pending litigation. The Board reconvened at 1:10 p.m. for presentations and discussions.

PRESENTATIONS CONT'D

Pharmacy Technician Specialized Function.

Presenters: Michael Erho, Interim Pharmacy Director
 Melaine Sublette, Pharmacy Resident
 Cristina DuVall, Pharmacy Resident

Michael Erho of Central Washington Hospital presented the pharmacy's proposal to expand the training and specialized functions of qualifying pharmacy technicians to include utilization of these technicians to verify the work of other technicians (tech check tech) in re-stocking sedation and anesthesia medication boxes; selection of pre-packaged IV medication; and restocking of adult emergency medication chart.

Specialized functions for pharmacy technicians currently in rule [WAC 246-901-035(1),(2)]:

- Unit dose medication checking.
- Preparation of intravenous admixture and other parenteral preparations.
- Automated drug distribution device stocking [WAC 246-871-030(4)(a)].

Proposal:

Sedation and Anesthesia Medication Boxes

- Technician restocks box according to drug list – verifying expiration dates
- Specialized Function Authorized Technician – verifies accuracy - right drug label and right dose

IV Medications

- Technician selects prepackage IV solution – matching drug label to patient label
- Specialized Function Authorized Technician – verifies accuracy - right drug label to right patient label

Adult Emergency Med Cart

- Used carts are returned to the pharmacy for restocking
- Technician using drug list matches dose and concentration for restocking
- Specialized Function Authorized Technician – verifies right drug, right concentration used for restocking
- Soon to expire drugs are flagged on outside of cart.

Revisions of Pharmacy Technician Utilization Plan:

- Minimum requirements for participation in the Technician Specialized Function
- Risk Management case review of medication errors.
- Quality assurance and reporting program
 - Minimum of 8 hour training per specialized function - taught by pharmacists
 - Written (80% competency level) & Practice Exams (99% competency level) must be completed before they can go on to practical experience.
 - Sedation/Anesthesia Med Box – 250 dose
 - IV Medications – 100 doses
 - Adult Emergency Med Cart – 150 dose
 - Practical Experience – 99% competency level
 - Sedation/Anesthesia Med Box – 500 dose
 - IV Medications – 300 doses
 - Adult Emergency Med Cart – 250 dose

During the practical experience all doses are checked for a third time by a pharmacist before being released/dispensed by the pharmacy.

Specialized Function Authorized Technicians will be audited 4 times in the first year and must re-qualify each year.

ACTION: Susan Teil-Boyer moved that the Board approve the proposal by Central Washington Hospital as a pilot project. The pilot will permit utilization of specialized functions for pharmacy technicians to check the work of another pharmacy technician in re-stocking sedation and anesthesia medication boxes; selection of pre-packaged patient specific IV medication (not to include patient's first time dose); and restocking of adult emergency medication carts. The Board requires that CWH report back in six months statistics on the number of doses, accuracy rates, any issues identified and the number of audits performed. Rosemarie Duffy 2nd.

MOTION CARRIED 5-0.

Bellegrave Pharmacy Telepharmacy Request Pharmacist Steve Singer from Bellegrave Pharmacy presented a proposal to provide telepharmacy services at Royal City Clinic located in an underserved area of the state. The policies and procedures proposed are currently being used at the Stillaguamish Clinic. These policy and procedures were approved by the Board in May 2007.

This proposal is supported by Wenatchee Valley Medical Center. WVMC currently oversees the operation at the Royal City Clinic.

ACTION: Susan Teil-Boyer moved that the Board approve the proposal by Bellegrove Pharmacy to provide telepharmacy services to the Royal City Clinic. The Board requests that Bellegrove Pharmacy provide an update on the Royal City Clinic program 6 months after implementation. Rosemarie Duffy 2nd. **MOTION CARRIED 5-0.**

DISCUSSION

Board Asked to Provide Input Regarding a Request before the Nursing Care Quality Assurance Commission. NCQAC has received a request for an advisory opinion regarding the delegation of routine prescription refills (renewals) to registered nurses according to specified protocol submitted by Snohomish County Community Health Center.

Tim Fuller provided the Board with background. The NCQAC has a formal process written in statute that permits requesters to receive an advisory opinion from the Commission. Proposal: Refill Protocol - Providers designate specific patients for refill protocol by noting in patient record. If the medication meets the criteria the Registered Nurse will send electronic refill request to the pharmacy. Originally, the protocol included delegation to Medication Assistants as well as RNs. MAs were later removed. RNs will not call in controlled substances and will attend annual pharmacy program training.

NCQAC has asked for comments from the Medical Quality Assurance Commission and the Board of Pharmacy regarding this proposal. Tim Fuller attended the NCQAC meeting where Dr. Tocher presented.

Issues:

- Renewal verses Refill
- Standing Orders
- Delegation of prescriptive authority to practitioners without like authority
- 30 day supply or 3 month supply
- Drug lists (misspelled drugs)
- Protocol inconsistent – RNs not authorized to refill controlled substances in one section but authorized in another.
- Would a prescription/request for refill for a legend from an unauthorized provider be a valid prescription?

The proposal was seen as reasonable, but lacked detail.

The Board will form a subcommittee to include Rosemarie Duffy, Vandana Slatter and Susan Teil-Boyer work with Tim in sharing the Board's concerns with the NCQAC.

Bill Fassett asked that the Board research whether nurses have the statutory authority to renew a prescription. Joyce Roper will talk with the AAG representing the Commission.

2007 – 08 Travel Plans. The Board is allotted seven out-of-state trips per fiscal year. Trips for 2007 – 2008 calendar were assigned as follows:

- NABP District 7 & 8 Joint Meeting, October 3-6, 2007 – Dan Connolly
- National Association of State Controlled Substance Scheduling Authorities Conference NASCSA, October 16-20, 2007 – Stan Jeppesen, Pharmacist Investigator

- NABP Annual Meeting, May 17-20, 2008 – Steven Saxe, Executive Director; Rosemarie Duffy
- University of Utah School on Alcoholism & Other Drug Dependencies, June 15-20, 2008 – Dan Connolly; Vandana Slatter; and Pharmacist Investigator (to be named)

Board, Commission and Committee Survey Results. The Board discussed the results of the BCC survey conducted by the office of Health Professions Quality Assurance to determine overall satisfaction. Board of Pharmacy member participation was good.

2007 – 2009 Biennium Budget. The Board reviewed a summary of the 07-09 biennium budget, which highlighted the differences from last biennium on discretionary spending categories.

Susan Teil-Boyer asked about the implication of the Board of Pharmacy becoming a commission. Discussion addressed the disparity in the compensation pay between a board and a commission.

Correspondence. The Board reviewed and discussed correspondence received on behalf of the Board.

- NABP –Observers on Accreditation Council for Pharmacy Education (ACPE) Site Visit. Regarding the University of Washington Accreditation.
- Required Use of Tamper-Resistant Prescription Pads – Tim Fuller distributed samples of tamper proof prescriptions. We have not received direction from the Department of Social and Health Services on the standards. The deadline for compliance is October 1, 2007.

Doug Beeman stated that the issue is the availability of the forms once the standards are established. Many pharmacies are scanning hard copy prescriptions. Tamper resistant features often makes these forms unsuitable for scanning. Medicaid – reimbursement issue.

Information regarding standards for tamper resistant prescriptions will be disseminated to practitioners once it becomes available.

By October 2008 all three requirements must be complied with. One or more industry-recognized feature designed to prevent:

1. Unauthorized copying or a completed or blank form;
 2. The erasure or modification of information written on the prescription by the prescriber;
 3. The use of counterfeit prescription forms.
- NABP has stopped giving the NAPLEX exam. The exam is expected to be reinstated beginning November. The Washington MPJE is still being administered.
 - Gary Harris asked, on behalf of Dan Connolly, Joyce Roper to comment on the Board's authority to require pharmacies to have Quality Improvement Programs as either a basic requirement in their operational procedures or as a requirement of a disciplinary settlement.

Joyce Roper cautioned the Board on adopting requirements for QI/QA programs or developing guidelines in this area. Although there is no specific statutory authority for the

Board to come up with QA programs, the Board's role is as a disciplinary authority setting minimal standards of care that if not met could lead to disciplinary action. She stated that generally people will look at QA programs as setting standard that are enforceable through disciplinary action rather than programs established to improve your practice. The Board's clear legislative goal is to disciplinary practitioners that do not met the minimum standards to protect the public as established in law. Ms. Roper stated that raising the bar by a government entity may be viewed as restricting persons or business from entering the practice.

Ms. Roper suggested that, independent from the Board, experts from pharmacy practice work with the program in the Department of Health in developing guidelines for the program to use to evaluate QA programs submitted by pharmacies. The program reviews QA programs developed by practitioners. Approved QA programs are afforded certain legal protections under disclosure.

Rules Workshop- Extended Care Facilities – Pharmaceutical Services – Disposal of Controlled Substances. Tim Fuller led the discussion on possible economic impacts the proposed rule may impose and methods to collect the necessary data. The Board looked at possible costs imposed by the rule on contract pharmacies that retain ownership of the drugs verses nursing homes registering with the DEA for drug disposal through a contacted pharmacy or reverse distributor. Factors for consideration included nursing home staff time, unit dose systems, automated drug devices, diversion risk, DEA registration, Board of Pharmacy controlled substance registration, contracted pharmacy services, and reverse distributors.

Business Meeting Adjourned

There being no further business, the Board adjourned at 4:40 p.m. The Board of Pharmacy will meet again on October 25, 2007 in Kent, Washington.

Respectfully Submitted by:

Doreen Beebe, Program Manager

Approved on October 25, 2007

*Rebecca Hille, Chair
Board of Pharmacy*